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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,639	05/09/2002	Luigi Naldini	131.3-US-WO	6785

22462 7590 12/15/2004

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/031,639	NALDINI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Guzo	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10, 13-16, 18-25 and 27-30 is/are rejected.
- 7) ☒ Claim(s) 11, 12, 17 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/1/02</u> .  | 6) <input checked="" type="checkbox"/> Other: <u>CRF Problem Report</u> .   |

### **Detailed Action**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Applicant is requested to return a copy of the attached CRF Diskette Problem Report with the reply.

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/131,671, filed 4/29/99 and the PCT/US/11097 application, filed 4/26/00. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be

submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

In the instant case, applicants claim priority for the PCT and 60/131,671 applications in the Declaration filed 5/9/02; therefore a Petition to accept the priority claim is not necessary. However, applicants must recite the priority claim on the first page of the specification or in an Application Data Sheet.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 8-10, 13-16, 18-25 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Dull et al.

Applicants claim a lentiviral (which can be based upon HIV-1) packaging system comprising a structural lentiviral vector system comprising a first lentiviral vector that encodes a gag, pol or gag and pol genes (which can be under control of a heterologous promoter such as a CMV promoter) and a RRE downstream of the structural gene(s) and a regulatory lentiviral vector comprising a rev gene (which can be operably linked to a heterologous regulatory element such as RSV U3 or HSV tk promoter) wherein the regulatory lentiviral vector is provided on a separate construct from the structural lentiviral vector and a lentiviral transfer vector comprising a heterologous gene operably linked to a regulatory element. The instant lentiviral packaging system also lacks a functional tat gene (which is mutated to be non-functional), comprises a heterologous viral env gene which can be on a separate construct and lacks the lentiviral accessory

genes vif, vpr, vpu and nef. Applicants also claim a method of producing a recombinant lentivirus comprising: (a) transfecting a packaging host cell with a lentiviral transfer vector comprising a heterologous gene operably linked to a regulatory element and the instantly claimed lentiviral packaging system and (b) recovering the recombinant lentivirus produced by the transfected packaging host cell.

Dull et al. (Cited by applicants, J. Virol., Nov. 1998, Vol. 72, No. 11, pages 8463-8471, see whole article, particularly the Abstract, the first eight paragraphs of the "Materials and Methods" section on pages 8464-8465, the first five paragraphs of the "Results" section and Fig. 4) recites a HIV-1 based packaging system comprising a structural vector system comprising a first lentiviral vector that encodes gag and pol genes under control of a CMV promoter and a RRE downstream of the gag/pol genes and a regulatory lentiviral vector comprising a rev gene (which can be operably linked to a heterologous regulatory element such as RSV U3 or HSV tk promoter) wherein the regulatory lentiviral vector is provided on a separate construct from the structural lentiviral vector and a lentiviral transfer vector comprising a heterologous gene operably linked to a regulatory element. The lentiviral packaging system disclosed by Dull et al. also lacks a functional tat gene (which is mutated to be non-functional), comprises a heterologous viral env gene (VSV-G) which can be on a separate construct and lacks the lentiviral accessory genes vif, vpr, vpu and nef. Applicants also claim a method of producing a recombinant lentivirus comprising: (a) transfecting a packaging host cell with a lentiviral transfer vector comprising a heterologous gene operably linked to a regulatory element and the instantly claimed lentiviral packaging system and (b)

Art Unit: 1636

recovering the recombinant lentivirus produced by the transfected packaging host cell.

Dull et al. therefore teaches the claimed invention.

Claims 8, 9, 13-15, 19-21, 23-25 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al. (WO 99/04026).

Applicants' invention is as described as in the above 35 USC 102(a) rejection over Dull et al.

Chen et al. (Cited by applicants, see whole document, particularly pages 3, 6-7, Examples 2 and 3, Figs. 2-4) recites a lentiviral (which can be HIV-1) packaging system comprising a first lentiviral vector comprising the gag and pol genes under control of a CMV promoter and a RRE downstream of the gag/pol genes, a regulatory lentiviral vector comprising the rev gene under control of a heterologous promoter and a vector comprising a heterologous env gene (VSV-G) and a lentiviral transfer vector comprising a heterologous gene under control of a regulatory element. Chen et al. therefore teaches the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1636

Claim 27 (and dependent claims) are vague in that there is no antecedent basis for the term "the heterologous inducible regulatory element".

Claims 11 and 14 are objected to because of the following informalities: A typographical error is present in Claims 11 and 14 as said claims begin with the word "he" rather than the word "The". Appropriate correction is required.

Claims 11-12, 17 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

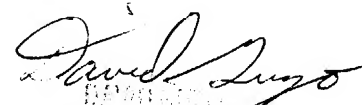
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
December 2, 2004



DAVID GUZO  
PATENT EXAMINER